

EXHIBIT R

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NINDS Multiple Sclerosis Information Page

Condensed from [Multiple Sclerosis: Hope Through Research](#)

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What is Multiple Sclerosis?

An unpredictable disease of the central nervous system, multiple sclerosis (MS) can range from relatively benign to somewhat disabling to devastating, as communication between the brain and other parts of the body is disrupted. Many investigators believe MS to be an autoimmune disease -- one in which the body, through its immune system, launches a defensive attack against its own tissues. In the case of MS, it is the nerve-insulating myelin that comes under assault. Such assaults may be linked to an unknown environmental trigger, perhaps a virus.

Most people experience their first symptoms of MS between the ages of 20 and 40; the initial symptom of MS is often blurred or double vision, red-green color distortion, or even blindness in one eye. Most MS patients experience muscle weakness in their extremities and difficulty with coordination and balance. These symptoms may be severe enough to impair walking or even standing. In the worst cases, MS can produce partial or complete paralysis. Most people with MS also exhibit paresthesias, transitory abnormal sensory feelings such as numbness, prickling, or "pins and needles" sensations. Some may also experience pain. Speech impediments, tremors, and dizziness are other frequent complaints. Occasionally, people with MS have hearing loss. Approximately half of all people with MS experience cognitive impairments such as difficulties with concentration, attention, memory, and poor judgment, but such symptoms are usually mild and are frequently overlooked. Depression is another common feature of MS.

Is there any treatment?

There is as yet no cure for MS. Many patients do well with no therapy at all, especially since many medications have serious side effects and some carry significant risks. However, three forms of beta interferon (Avonex, Betaseron, and Rebif) have now been approved by the Food and Drug Administration for treatment of relapsing-remitting MS. Beta interferon has been shown to reduce the number of exacerbations and may slow the progression of physical disability. When attacks do occur, they tend to be shorter and less severe. The FDA also has approved a synthetic form of myelin basic protein, called copolymer I (Copaxone), for the treatment of relapsing-remitting MS. Copolymer I has few side effects, and studies indicate that the agent can reduce the relapse rate by almost one third. Other FDA approved drugs to treat relapsing forms of MS in adults include teriflunomide and dimethyl fumarate. An immunosuppressant treatment, Novantrone (mitoxantrone), is approved by the FDA for the treatment of advanced or chronic MS. The FDA has also approved dalfampridine (Ampyra) to improve walking in individuals with MS.

One monoclonal antibody, natalizumab (Tysabri), was shown in clinical trials to significantly reduce the frequency of attacks in people with relapsing forms of MS and was approved for marketing by the U.S. Food and Drug Administration (FDA) in 2004. However, in 2005 the drug's manufacturer voluntarily suspended marketing of the drug after several reports of significant adverse events. In 2006, the FDA again approved sale of the drug for MS but under strict treatment guidelines involving infusion centers where patients can be monitored by specially trained physicians.

While steroids do not affect the course of MS over time, they can reduce the duration and severity of attacks in some patients. Spasticity, which can occur either as a sustained stiffness caused by increased muscle tone or as spasms that come and go, is usually treated with muscle relaxants and tranquilizers such as baclofen, tizanidine, diazepam, clonazepam, and dantrolene. Physical therapy and exercise can help preserve remaining function, and patients may find that various aids -- such as foot braces, canes, and walkers -- can help them remain independent and mobile. Avoiding excessive activity and avoiding heat are probably the most important measures patients can take to counter physiological fatigue. If psychological symptoms of fatigue such as depression or apathy are evident, antidepressant medications may help. Other drugs that may reduce fatigue in some, but not all, patients include amantadine (Symmetrel), pemoline (Cylert), and the still-experimental drug aminopyridine. Although improvement of optic symptoms usually occurs even without treatment, a short course of treatment with intravenous methylprednisolone (Solu-Medrol) followed by treatment with oral steroids is sometimes used.

What is the prognosis?

A physician may diagnose MS in some patients soon after the onset of the illness. In others, however, doctors may not be able to readily identify the cause of the symptoms, leading to years of uncertainty and multiple diagnoses punctuated by baffling symptoms that mysteriously wax and wane. The vast majority of patients are mildly affected, but in the worst cases, MS can render a person unable to write, speak, or walk. MS is a disease with a natural tendency to remit spontaneously, for which there is no universally effective treatment.

What research is being done?

The National Institute of Neurological Disorders and Stroke (NINDS) and other institutes of the National Institutes of Health (NIH) conduct research in laboratories at the NIH and also support additional research through grants to major medical institutions across the country. Scientists continue their extensive efforts to create new and better therapies for MS. One of the most promising MS research areas involves naturally occurring antiviral proteins known as interferons. Beta interferon has been shown to reduce the number of exacerbations and may slow the progression of physical disability. When attacks do occur, they tend to be shorter and less severe. In addition, there are a number of treatments under investigation that may curtail attacks or improve function. Over a dozen clinical trials testing potential therapies are underway, and additional new treatments are being devised and tested in animal models.

In 2001, the National Academies/Institute of Medicine, a Federal technical and scientific advisory agency, prepared a strategic review of MS research. To read or download the National Academies/Institute of Medicine report, go to: "[Multiple Sclerosis: Current Status and Strategies for the Future](#)."

NIH Patient Recruitment for Multiple Sclerosis Clinical Trials


- ▶ [At NIH Clinical Center](#)
- ▶ [Throughout the U.S. and Worldwide](#)
- ▶ [NINDS Clinical Trials](#)

Organizations

[Multiple Sclerosis Association of America](#)

375 Kings Highway North
Cherry Hill, NJ 08034
webmaster@msassociation.org
<http://www.mymsaa.org> 
Tel: 856-488-4500; 800-532-7667
Fax: 856-661-9797


[Multiple Sclerosis Foundation](#)

6520 North Andrews Avenue
Ft. Lauderdale, FL 33309-2130
support@msfocus.org
<http://www.msfocus.org> 
Tel: 954-776-6805; 888-MSFOCUS (673-6287)
Fax: 954-351-0630

[Accelerated Cure Project for Multiple Sclerosis](#)

460 Totten Pond Rd. Suite 420
Waltham, MA 02451
info@acceleratedcure.org
<http://www.acceleratedcure.org> 
Tel: 781-487-0008
Fax: 781-487-0009

[National Multiple Sclerosis Society](#)

733 Third Avenue
3rd Floor
New York, NY 10017-3288
ContactUsNMSS@nmss.org
<http://www.nationalmssociety.org> 
Tel: 800-FIGHT-MS (800-344-4867)
Fax: 212-986-7981

[American Autoimmune Related Diseases Association](#)

22100 Gratiot Avenue
Eastpointe, MI 48021-2227
aarda@aarda.org

[National Rehabilitation Information Center \(NARIC\)](#)

8400 Corporate Drive
Suite 500
Landover, MD 20785

<http://www.aarda.org>

Tel: 586-776-3900; 800-598-4668

Fax: 586-776-3903

naricinfo@heitechservices.com

<http://www.naric.com>

Tel: 301-459-5900; 800-346-2742; 301-459-5984 (TTY)

Fax: 301-562-2401

Clearinghouse on Disability Information

Special Education & Rehabilitative Services
Communications & Customer Service Team
550 12th Street, SW, Rm. 5133
Washington, DC 20202-2550

<http://www.ed.gov/about/offices/list/osers>

Tel: 202-245-7307; 202-205-5637 (TTD)

Fax: 292024507636

National Ataxia Foundation (NAF)

2600 Fernbrook Lane North
Suite 119
Minneapolis, MN 55447-4752

naf@ataxia.org

<http://www.ataxia.org>

Tel: 763-553-0020

Fax: 763-553-0167

National Organization for Rare Disorders (NORD)

55 Kenosia Avenue
Danbury, CT 06810

orphan@rarediseases.org

<http://www.rarediseases.org>

Tel: 203-744-0100; Voice Mail: 800-999-NORD (6673)

Fax: 203-798-2291

Well Spouse Association

63 West Main Street
Suite H
Freehold, NJ 07728

info@wellspouse.org

<http://www.wellspouse.org>

Tel: 800-838-0879; 732-577-8899

Fax: 732-577-8644

Paralyzed Veterans of America (PVA)

801 18th Street, NW
Washington, DC 20006-3517

info@pva.org

<http://www.pva.org>

Tel: 202-USA-1300 (872-1300); 800-555-9140

Fax: 202-785-4452

Myelin Repair Foundation

18809 Cox Avenue
Suite 190
Saratoga, CA 95070

info@myelinrepair.org

<http://www.myelinrepair.org/>

Tel: 408-871-2410

Related NINDS Publications and Information

Multiple Sclerosis: Hope Through Research

Multiple Sclerosis (MS) information sheet compiled by the National Institute of Neurological Disorders and Stroke (NINDS).

Neurological Diagnostic Tests and Procedures

Fact sheet on neurological diagnosis and testing, prepared by the National Institute of Neurological Disorders and Stroke (NINDS).

Small Trial Shows Daclizumab Add-On Therapy Improves Multiple Sclerosis Outcome

May 2004 press release on a clinical trial showing improved patient outcome after use of the drug daclizumab.

Old Drug, New Use: New Research Shows Common Cholesterol-Lowering Drug

Reduces Multiple Sclerosis Symptoms in Mice

January 2003 news summary on studies suggesting that statin drugs may be useful for multiple sclerosis.

▶ **Brain Produces New Cells in Multiple Sclerosis**

February 2002 news summary on brain repair in multiple sclerosis.

▶ **Biomarkers in Multiple Sclerosis - Workshop Summary**

Biomarkers in Multiple Sclerosis - Workshop Summary

▶ **Genetics and Multiple Sclerosis: Future Prospects Workshop**

Genetics and Multiple Sclerosis: Future Prospects Workshop

▶ **Multiple Sclerosis and Chemokines: Prospects for Therapeutic and Prophylactic Intervention**

Health Disparities Working Group Meeting: Cognitive and Emotional Health Multiple Sclerosis and Chemokines: Prospects for Therapeutic and Prophylactic Intervention

Publicaciones en Español

▶ **Esclerosis Múltiple: Esperanza en la Investigación**

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